12-19-01

510(K) Summary

Disc-O-Tech Medical Technologies, Ltd.
Fixion Interlocking Intramedullary Nailing System

Company Name
Disc-O-Tech Medical Technologies, Ltd.
3 Hasadnaot St., Herzelia, 46728, Israel

Submitter's Name and Contact Person
Elad Magal
Disc-O-Tech Medical Technologies, Ltd.
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Date Prepared
October 2001

Trade/Proprietary Name
Fixion™ Interlocking Intramedullary Nailing System (Fixion IL Nail)

Classification Name
Intramedullary Fixation Rod
21 CFR § 888.3020
Class II

Predicate Devices
1. Fixion Interlocking Intramedullary Nailing System (Fixion IL Nail) by the company - K002783
2. Fixion Intramedullary Nailing System (Fixion IM Nail) by the company – K990717, K003212, K003215, K010901
3. Unreamed Humeral Nail by Synthes – K933518
4. Unreamed Tibial Nail by Synthes - K914453
5. Unreamed Femoral Nail by Synthes - K923580
6. Ti Distal Femoral Nail by Synthes - K970733
7. True/Flex Upper Extremity IM Nail by Encore (Applied Osteo Systems, Inc.) - K902264

Performance Standards
The following standards were used:
1. The Fixion IL Nail is manufactured from 316L Stainless Steel, which meets the requirements of ASTM F138 - Standard Specification for Wrought 18 Chromium – 14 Nickel – 2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS

S31673).
2. The Fixion IL Nailing System accessories incorporate surgical grade stainless steel and silicone.
3. The Fixion IL Nail is designed to meet the requirements of ASTM F565 – Standard practice for Care and Handling of Orthopedic Implants and Instruments.
4. The 4 point bending mechanical testing was performed according to ASTM F1264-99 - Standard for Mechanical Performance Considerations for Intramedullary Fixation Devices.

Intended Use
The Fixion™ Interlocking Intramedullary Nail is intended for use in fixation of various types of fractures, including diaphyseal fractures and short distal or proximal fragments in the long bones.

System Description
The Fixion Interlocking Intramedullary Nailing System consist of the following main components:
1. The **Nail Implant** is an expandable non-slotted stainless steel cylindrical tube, with a cap protected, female threaded proximal end with holes for interlocking screws to lock the nail in the bone. The **Nail Implant** may also have both proximal and distal ends with holes for interlocking screws.
2. The **Instrument Set** consists of a few accessories used during insertion and removal (if required) of the Nail Implant.
3. The **Inflation Device** is a single-use, manual, plastic pump to be filled with sterile inflation liquid.

Once the nail is positioned within the medullary canal, rotation of the pump handle allows for nail diameter increase to its intended diameter under x-ray and controlled pressure. Interlocking screws may be used to lock the nail inside the bone.

Substantial Equivalence
The Fixion IL Nail is substantially equivalent to the Fixion IL Nail currently cleared for marketing under 510(k) K002783.
The modified Fixion IL Nail has the following similarities to that which previously received 510(k) concurrence:
- Has an equivalent intended use
- Has basically the same operating principles
- Incorporates similar design
- Incorporates the same materials and processes
- Is sterilized and packed, basically, in the same manner.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 9 2001

Mr. Elad Magal
General Manager
Disc-O-Tech Medical Technologies, Ltd.
3 Hasadnaot Street
Herzelia, 46728
Israel

Re: K013449
Trade/Device Name: Fixion Interlocking Intramedullary Nailing System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: II
Product Code: HSB
Dated: October 15, 2001
Received: October 17, 2001

Dear Mr. Magal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

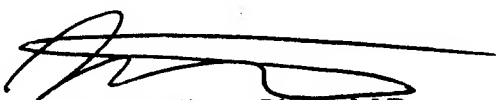
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K013449

Device Name: Fixion™ Interlocking Intramedullary Nailing System (Fixion™ IL Nail)

Indication for Use: The Fixion™ Interlocking Intramedullary Nail is intended for use in fixation of various types of fractions, including diaphyseal fractures and short distal or proximal fragments in the long bones.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes (per 21 CFR 801.109) OR Over the Counter Use No

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013449